- means for storing said processed information in a cell management data base.--

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REMARKS

It is believed that this application has been amended in a manner that places it in condition for allowance at the time of the next Official Action.

In the outstanding Official Action, claims 1-9, 20-31, 35 and 36 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

While the outstanding Official Action objected to the phrase "immunity information", the term "immunity information" is defined in the present specification at page 2, lines 2-13. "Immunity information" relates to viral, parasitic, and bacterial infections encountered by an immunocompetent cell. "Immunity information" is stored in the walls of immunocompetent cells such as lymphocytes. Thus, it is respectfully submitted that the term is definite to one of ordinary skill in the art.

The outstanding Official Action also objected to the term "information characteristic". The term "information characteristic" refers to the status of a human or animal subject and includes bioelectronic information resulting from processing measurements on blood, information obtained by processing sensible crystallization images of blood previously collected on

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a human or animal subject, or information obtained from a capillary study on elements of the human or animal subject's hair. It is respectfully submitted that one of ordinary skill in the art would also find this term definite.

As to the objection of the term "status-characterizing information", the term has been replaced by "status characterizing information by processing measurements made on samples of blood and other fluids and secretions and/or hair".

As claims 8-9 and 30-31 have been cancelled, it is respectfully submitted that the contentions relating to these claims are now moot.

The outstanding Official Action also objected to the term "elements" recited in claims 5 and 27. The term "capillary study on elements of human or animal subject's hair system" has been replaced by the phrase "measuring physical and/or biological characteristics done on samples of hair from said human or animal subject". Thus, in light of the present amendment, it is believed that claims 5 and 27 are definite to one of ordinary skill in the art.

In claims 7 and 28, the term "expert system" is objected to for allegedly being vague and indefinite. An expert system is a dedicated computer system specifically programmed for executing rules on data entered into a system. Thus, it is believed that the term is definite to one of ordinary skill in the art.

The Official Action also objected to the terms "initial step" and "annihilation". As to the term "initial step", claim 20 has been amended so that the phrase "an initial step for" has been deleted and the phrase "a step of" has been inserted. However, applicant traverses the contention that the term "annihilation" is indefinite. The step of annihilation and the reason why antibodies have to be annihilated with a batch of immunocompetent cells is explained on page 10, lines 16-22 of the present specification. Thus, it is believed that the term "annihilated" is definite.

In claims 22 and 26, the terms "sequence" and "sensible crystallization image" were objected to for allegedly being indefinite. Claim 22 has been amended so that the term "sequence" is no longer recited in the claim. Claim 26 has been cancelled.

Thus, in light of the present amendment, it is respectfully submitted that the claimed invention is definite to one of ordinary skill in the art.

In the outstanding Official Action, claims 1, 23, 35 and 36 were rejected under 35 USC §102(a) as allegedly being anticipated by LEFESVRE WO 99/53030. This rejection is respectfully traversed.

Applicant respectfully submits that the LEFESVRE publication fails to disclose or suggest the claimed invention. It is believed that the publication fails to disclose the steps

of gathering, during successive collection of batches, information characteristic of the status of health and/or the psychological status of subjects, this status-characterizing information being obtained by processing measurements made on samples of blood, fluid and secretion and/or hair collected on subjects.

Moreover, applicant believes that LEFESVRE does not disclose a process for determining parameters of a deferred-use protocol for immunocompetent cells by successively collecting and processing a subject's identity data.

Thus, it is respectfully submitted that LEFESVRE fails to disclose each and every recitation set forth in the claimed invention. As such, applicant respectfully submits that LEFESVRE fails to anticipate or render obvious the claimed invention.

Claims 2-9, 20-22 and 24-31 were rejected under 35 USC §103(a) as allegedly being unpatentable over LEFESVRE in view of SHIOTA et al. ("Special Capabilities of Micro-Multiplane Transesophageal Echocardiography for Studying Congenital Heart Disease Surgery in Neonates, Infants and Children, Journal of the American College of Cardiology, February 1998, Volume 31, Issue 21001, Supplement 1, pages 247A-248A), or in view of EGGER et al. ("Changes in the polymorphonuclear leukocyte function of blood samples induced by storage time, temperature and agitation, Journal of Immunological Methods, August 1997, Volume 206, Issue 1-2, pages 61-71), or in view of CONNELLY et al. ("The clinical

workstation as a means of improving laboratory use, Clinica Chimica Acta. April 1996, Volume 248, Issue 1, pages 51-64), or in view of LAKEW et al. ("Combined immunomagnetic cell sorting and ELISPOT assay for the phenotypic characterization of specific antibody-forming cells, Journal of Immunological Methods, April 1995, Volume 203, Issue 2, pages 193-198), or in view of NICOLINI C. ("Supramolecular architecture and molecular bioelectronics, Thin Solid Films, September 1996, Volume 284-285, pages 1-5), or in view of STOYLOVA et al. ("Structural determination of lipid-bound human blood coagulation factor IX, Biochiumica et Biophysica Acta (BBA)/Protein Structure and Molecular Enzymology, April 1998, Volume 1383, Issue 2, pages 175-178), or in view of PIO et al. (Granule associated DNase in T4 and T8 lymphocytes from patients with autoimmune diseases, Biochimica et Biophysica Acta (BBA)/Molecular Basis of Disease, February 1998, Volume 1406, Issue 1, pages 51-61), or in view of PLANTIKOW-VOBGATTER et al. ("Application of an ETV-ICP system for the determination of elements in human hair, Spectrochimica Acta Part B: Atomic Spectroscopy, January 1996, Volume 51, Issue 2, pages 261-270). This rejection is respectfully traversed.

The present invention is directed to a method for managing batches of immunocompetent cells, which fully integrates the dimension of subject's identity and status of health.

However, LEFESVRE discloses a method in which information is collected and stored in a central management site.

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The method by LEFESVRE is limited to data collected during batch collection.   Moreover, all that is required to merely identify the origin of batches, the sites wherein the batches are stored, and their conditions of preparation and storage.   In fact, LEFESVRE discloses a management method mainly oriented towards logistic matters and does not teach or suggest the deferred-use of a batch of cells.   In addition, LEFESVRE does not implement a time dimension of successively collecting batches of cells along a period of a subject's life.   Thus, applicant respectfully submits that LEFESVRE fails to render obvious the claimed invention.

In an effort to remedy the deficiency of LEFESVRE, the outstanding Official Action proposes a combination of LEFESVRE and SHIOTA et al., or EGGER et al., or CONNELLY et al., or LAKEW et al., or NICOLINI et al., or STOYLOVA et al., or PIO et al., or PLANTIKOW-VOBGATTER et al.   However, it is respectfully submitted that these publications fail to remedy the deficiencies of LEFESVRE.   It is believed that the cited publications fail to disclose a method for managing batches of immunocompetent cells collected from human or animal subjects for deferred use, as set forth in the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is respectfully believed that this application is now in condition for allowance.   Allowance and
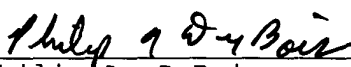
passage to issue on that basis are accordingly respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 1 has been amended as follows:

--1. (amended) A method for managing batches of immunocompetent cells collected from human or animal subjects for deferred use, comprising for each of said human or animal subjects the following steps:

- conditioning and preserving successively collected batches of immunocompetent cells, into one or more storage centers, and

- constituting and enhancing from collected batches a personal library of immunocompetent cells, said personal library cumulating a sum of immunity information stored in the walls of the collected immunocompetent cells, or
[characterized in that is further comprises:]

- during successive collections or batches, gathering information characteristic of the status of health and/or the psychological status of said human or animal subject, said status-characterizing information being obtained by processing measurements made on samples of blood and/or fluid and secretions and/or hair collected said human or animal subject, said status-characterizing information gathering being effected before or during the immunocompetent cells collection, [and]

- processing said [characteristic] status-characterizing information for determining the subject's identity

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data [parameters of a deferred use protocol for immunocompetent cells from said human or animal subject's personal library],

- storing, all along said steps, the subject's identify data into a cell management database,

- upon a request for re-use, performing an identification of the personal batches of cells by consulting said cell management database, and receiving from said cell management database said subject's identity data obtained by successive status-characterizing information processing, and

- determining parameters of a deferred-use protocol for immunocompetent cells from said human or animal subject's personal library, by processing said successively collected subject's identity data.--

Claim 3 has been amended as follows:

--3. (amended) The method according to claim [2] 1, characterized in that the status-characterizing information comprise bioelectronic information resulting from processing respective measures of pH, oxidation-reduction potential Rh2 and resistivity ρ of blood previously collected on said human or animal subject (Vincent's bioelectronic method).--

Claim 20 has been amended as follows:

--20. (amended) The method according to claim 1, characterized in that it further comprises, before the step for cryo-preserving a batch of immunocompetent cells, [an initial

step for] <u>a step of</u> cryogenizing said batch in view of annihilating antibodies present within said batch.--

        Claim 22 has been amended as follows:

        --22. (amended) The method according to claim 1, characterized in that it further comprises, during [a sequence for] conditioning a batch of immunocompetent cells previously collected, a step for immunomagnetically selecting purified lymphocytes or monocytes.--

        Claim 23 has been amended as follows:

        --23. (amended) A system for managing batches of immunocompetent cells collected from human or animal subjects for their deferred use, [implementing the method according to claim 1,] said system comprising for each of said human or animal subjects:

        - means for conditioning and preserving batches of immunocompetent cells successively collected, into one or more storage centers, [and]

        - means for constituting and enhancing from said collected batches a personal library of immunocompetent cells, said personal library cumulating a sum of immunity information stored in <u>the walls of</u> collected immunocompetent cells, [characterized in that it further comprises:]

        - means for gathering<u>, during successive collections of batches,</u> information that are characteristic of said human or animal subject's status <u>of health and/or psychological status,</u>

before or during immunocompetent cells collection, [and] <u>said</u>
<u>status characterizing information being obtained by processing</u>
<u>measurements made on samples of blood and/or fluid and secretions</u>
<u>and/or hair collected on said human or animal subject,</u>

     - means for processing said status-characterizing
information in view of determining [parameters for a deferred-use
of immunocompetent cells from said human or animal subject's
personal library] <u>said subject's identity data,</u>

     <u>- means for storing said subject's identity data</u>
<u>successively determined into a cell management database,</u>

     <u>- means for performing, upon a request for re-use, an</u>
<u>identification of the personal batches of cells to including</u>
<u>means for consulting said cell management database, and</u>

     <u>- means for determining parameters of a deferred-use</u>
<u>protocol for immunocompetent cells from said human or animal</u>
<u>subject's personal library, by processing said successively</u>
<u>collected subject's identity data.</u>--

     Claim 35 has been amended as follows:

     --35. (amended) A method for determining parameters of
a protocol for a deferred use of immunocompetent cells from a
human or animal subject's personal library, said personal library
cumulating a sum of immunity information stored in <u>the walls of</u>
the immunocompetent cells successively collected and conditioned
under the form of batches preserved in one or more storage
centers, characterized in that said method comprises:

- measuring physical and/or biological characteristics done on samples of fluid and/or hair from said human or animal subject before or during the collection of immunocompetent cells,

- collecting information characteristic of the status of health and/or the psychological status of said human or animal subject's status resulting from said measurements, said status characterizing information being obtained by processing measurements made on samples of blood and/or fluid and secretions and/or hair collected on said human or animal subject,

- processing said characteristic information in an information system for determining parameters of said deferred-use protocol, and

- storing said processed information in a cell management data base.--

Claim 36 has been amended as follows:

--36. (amended) A system for determining parameters of a protocol for a deferred use of immunocompetent cells from a human or animal subject's personal library, said personal library cumulating a sum of immunity information stored in the walls of the immunocompetent cells successively collected and conditioned under the form of batches preserved in one or more storage centers, characterized in that said system comprises:

- means for measuring physical and/or biological characteristics done on samples of fluid and/or hair from said

human or animal subject before or during the collection of
immunocompetent cells,

- means for collecting information characteristic <u>of</u>
<u>the status of health and/or the psychological status</u> of said
human   or   animal   subject's   status   resulting   from   said
measurements, <u>said   status   characterizing   information   being</u>
<u>obtained by processing measurements made on samples of blood</u>
<u>and/or fluid and secretions and/or hair collected on said human</u>
<u>or animal subject,</u>

- means for processing said characteristic information
in an information system to determine parameters of said
deferred-use protocol, and

- means for storing said processed information in a
cell management data base.--